LIDOER- lidocaine hcl cream Diabetic Supply of Suncoast, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

LIDOER

DRUG FACTS

Active ingredient and Purpose

Active ingredient	Purpose		
Lidocaine HCL 4%	Topical analgesic		

Use

For the temporary relief of pain.

Warnings

For external use only. Avoid contact with the eyes.

Do not use

in large quantities, particularly over raw surfaces, or blistered areas.

Stop use and ask a doctor if

condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

If pregnant or breast feeding,

ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help, or contact a Poison Control Center immediately.

Directions

- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: consult a doctor

Other information

- store in a cool dry place between (59-86°F)15-30°C
- don't use if seal over cap is broken, torn, or missing

Inactive ingredients

c9-11 alkane/cycloalkane, cetostearyl alcohol, imidurea, menthol, methylparaben, mineral oil, peg-150 stearate, petrolatum, polysorbate 60, propylene glycol, propylparaben, steareth-20, stearic acid, trideceth-12, water

Questions or comments?

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Advocatemeters.com

Distributed by:

Diabetic Supply of Suncoast, Inc.

PO Box 2102, Vega Alta, PR 00692

Principal Display Panel

NDC 71814-121-04 | Made in the USA





PAIN RELIEVING Topical Analgesic Cream Lidocaine HCL 4% MAXIMUM STRENGTH 4 oz (113 g)

LIDOER

lidocaine hcl cream

Product Information	Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71814-121	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
MENTHOL (UNII: L7T10EIP3A)		
PEG-150 STEARATE (UNII: 7BSG7DF10Q)		
PETROLATUM (UNII: 4T6H12BN9U)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
POLYSORBATE 60 (UNII: CAL22UVI4M)		
STEARETH-20 (UNII: LOQ8IK9E08)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
PROPYLPARABEN (UNII: Z8IX2SC10H)		
TRIDECETH-12 (UNII: YFY3KG5Y7O)		
WATER (UNII: 059QF0KO0R)		
C9-11 ALKANE/CYCLOALKANE (UNII: 3EZ541F5MW)		
IMIDUREA (UNII: M629807ATL)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
MINERAL OIL (UNII: T5L8T28FGP)		

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:71814-121- 04	113 g in 1 JAR; Type 0: Not a Combination Product	06/01/2018	01/01/2021

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/01/2018	02/28/2023

Labeler - Diabetic Supply of Suncoast, Inc. (043081723)

Revised: 11/2021 Diabetic Supply of Suncoast, Inc.